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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,866

09/28/2006

Masanobu Kobayashi

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EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

05/27/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,866	<b>Applicant(s)</b> KOBAYASHI ET AL.	
	<b>Examiner</b> MEERA NATARAJAN	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 17, 41-43 and 45-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 17, 41-43, 45-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/02/2009 has been entered.
2. Accordingly, Claims 1, 10, 17, 41-43, 45-53 are pending and will be examined on the merits.

### ***New Grounds of Rejection***

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 10, 17, 41, 46, 48, 50-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Green et al. (US Patent 7268136)
5. The claims are drawn to a method of screening for a therapeutic agent for cancer, an apoptosis inducing agent, or an anti-cancer agent, comprising the use of

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purified Pim-1 or a partial peptide or salt thereof. The method comprises contacting purified Pim-1 with a test substance that inhibits the activity of Pim-1.

6. Green et al. teach compounds which are inhibitors of protein kinases, particularly Pim-1. Green et al. also disclose compositions comprising the compounds and methods of using the compositions in the treatment of various disorders. Green et al. disclose the following "the activity of a compound utilized in this invention as an inhibitor of PIM-1, CDK-2, SRC, or GSK-3, may be assayed in vitro, in vivo or in a cell line. In vitro assays include assays that determine inhibition of either the phosphorylation activity or ATPase activity of activated PIM-1, CDK-2, SRC, or GSK-3. Alternate in vitro assays quantitate the ability of the inhibitor to bind to PIM-1, CDK-2, SRC, or GSK-3. Inhibitor binding may be measured by radiolabelling the inhibitor prior to binding, isolating the inhibitor/PIM-1, CDK-2, SRC, or GSK-3 complex and determining the amount of radiolabel bound. Alternatively, inhibitor binding may be determined by running a competition experiment where new inhibitors are incubated with PIM-1, CDK-2, SRC, or GSK-3 bound to known radioligands" (See column 64, lines 28-41). Green et al. disclose the active method steps of the claimed invention. Green et al. disclose compounds may be assayed in vitro to determine phosphorylation inhibition of Pim-1. Green et al. further disclose these compounds which inhibit protein kinases, in particular Pim-1 are useful in treating various diseases such as cancer.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 42, 43, 45, 47, and 49 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Green et al. (US Patent 7268136) in view of Whitmarsh et al.

(Methods in Enzymology, Vol. 332, pp.319-336, 2001).

10. The claims are drawn to a method of screening for substances that inhibit the activity of Pim1 comprising contacting a test substance with purified Pim1 and detecting the phosphorylation activity of Pim1 using an antibody or a gene reporter assay that is activated in response to binding of a Pim1 phosphorylation substrate.

11. The teachings of Green et al. have been presented in the 102(e) rejection set forth above. Green et al. does not teach detecting phosphorylation using a reporter gene assay. This deficiency is made up for by Whitmarsh et al.

12. Whitmarsh et al. teach analyzing JNK and p38 mitogen-activated protein kinase activity. Whitmarsh et al. disclose several protocols for measuring activation state and protein kinase activity that are well known in the art. Whitmarsh et al. disclose the use of a reporter gene assay for assessing JNK and p38 activity in cells on p. 24. The

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method recited is a generic method well known in the art to determine activation (ie. phosphorylation). Whitmarsh discloses "the phosphorylation of the fusion protein by the protein kinase leads to increased transcription of the luciferase gene and the resulting luciferase protein can be assayed enzymatically with a luminescent substrate"

13. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the reporter gene assay taught by Whitmarsh et al. to determine phosphorylation activity of Pim-1 in the method taught by Green et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Whitmarsh et al. and Green et al. because reporter gene assays help to target specific activators and Green et al. disclose inhibitors of Pim-1 can be assayed for phosphorylation activity.

### ***Conclusion***

14. Claims 1, 10, 17, 41-43, 45-53 are rejected.

15. No Claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643